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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,984	08/14/2008	Sascha Krueger	2004P00437WOUS	3939
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PHILIPS INTELLECTUAL PROPERTY & STANDARDS				
P.O. BOX 3001				
BRIARCLIFF MANOR, NY 10510				
EXAMINER				
COOK, CHRISTOPHER L.				
ART UNIT		PAPER NUMBER		
3737				
NOTIFICATION DATE		DELIVERY MODE		
05/09/2012		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

vera.kublanov@philips.com
debbie.henn@philips.com
marianne.fox@philips.com

Office Action Summary

Application No.

10/597,984

Applicant(s)

KRUEGER ET AL.

Examiner

CHRISTOPHER COOK

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2012.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-10 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-10 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-893)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____
- Paper No(s)/Mail Date ____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/07/2012 has been entered.

Claim Objections

2. Claim 4 is objected to because of the following informalities: Claim 4 is objected to because it appears to be redundant to the amendment of Claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 9 are rejected because the step of "optimizing a quality dimension" is confusing since it is unclear what an "optimized quality dimension" actually is. Claim 1 is also rejected because it is unclear how the correcting step takes into account the orientation of the localizers if the orientation is not indicated. For example, as previously set forth the localizers may indicate position,

orientation and/or shape (emphasis added). Thus, the orientation may not be indicated.

Claim 9 appears to have a similar issue.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-5 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,892,090 to *Verard et al.* "*Verard*" in view of U.S. Publication No. 2005/0065434 to *Bavaro et al.* "*Bavaro*" or U.S. Patent No. 7,366,562 to *Dukesherer et al.* "*Dukesherer*".

With respect to Claims 1-5 and 8-10, *Verard* discloses a method and device for determining the position of an instrument in a vascular system comprising: more than one electromagnetic localizer for determining the

position/orientation of the catheter with respect to external field generators (Column 2, Lines 30-35; Column 3, Lines 38-58). *Verard* further discloses an imaging device (14 in Fig. 1), configured to capture volumetric scan data, a data processing unit (16 in Fig. 1) and a display (18 in Fig. 1). *Verard* discloses wherein *"Position data such as location and/or orientation data from the tracking subsystem 20 is in turn relayed to the data processor 16. The data processor is adapted to receive position/orientation data from the tracking subsystem 20 and operable to render a volumetric perspective image and/or a surface rendered image of the region of interest"* (Column 4, Lines 8-20). Examiner notes that the region of interest includes a vessel or a cavity within the patient (Column 2, Line 67-Column 3, Line 1). In one embodiment, *Verard discloses* wherein a "secondary image" (e.g. surface rendered image) is displayed with an indicia or graphical representation which corresponds to the location of the surgical instrument within an air passage. *Verard* also discloses wherein the surgical navigation system may also incorporate atlas maps (3D or 4D) which may be registered with patient specific scan data or generic anatomical models (e.g. heart models) (Column 7, Lines 9-16). Examiner contends that either the "secondary image" or the atlas maps registered to the image data are considered to be a "vascular map". Furthermore, to *"...enhance visualization and refine accuracy of the displayed image data, the surgical navigation system can use prior knowledge such as the segmented vessel structure to compensate for error in the tracking subsystem or for inaccuracies caused by an anatomical shift*

*occurring since acquisition of scan data. For instance, it is known that the surgical instrument being localized is located **within** a given vessel and, therefore should be displayed **within** the vessel. Statistical methods can be used to determine the most likely location; within the vessel with respect to the reported location and then compensate so the display accurately represents the instrument within the center of the vessel"* (Column 6, Lines 52-63). Examiner contends that "compensating for error" is considered to be a correction if the instrument is located outside the vessel. Moreover, the statistical methods used by *Verard* to determine the "most likely" location would include the deviation of the measured position/orientation to the vascular layout (e.g. centerline) defined by the vascular map.

However, *Verard* does not expressly disclose taking into account a distance between the first and second localizers to also correct the displayed location of the localization sensors.

Bavaro teaches from within a similar field of endeavor with respect to localizing interventional medical devices wherein a device such as a guide wire is fitted with a series of markers at preselected (e.g. known, fixed, predefined) separations distances (Paragraphs [0039] and [0045]-[0046]).

Similarly, *Dukesherer* teaches from within a similar field of endeavor with respect to surgical navigation (Abstract) wherein a first localization coil is provided at a known distance from a second coil in order to compensate for any error in the sensed location signal (Column 28, Lines 25-40).

Therefore, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the system and method for determining the position of an instrument in a vascular system as described by Verard, particularly the correcting means to take into account a predefined, fixed separation distance from each localizer as described by *Bavaro/Dukesherer* in order to accurately represent the interventional device on a display. Examiner notes that such a modification would improve the guidance of such devices within the body and requires nothing more than the mere combination of known prior art elements and techniques to yield predictable results, which has previously been held as unpatentable (see for precedent *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385). Examiner notes that the modified device "optimizes" the displayed location by equally (e.g. same "weight") taking into account a predefined, fixed distance between the localizers and the localizers' distance from the vascular map (e.g. layout). Moreover, the "real-time" (Column 4, Lines 35-50) tracking/correcting of the displayed representation of the surgical device is considered to be a "local" or "spatial" continuous transformation

With respect to Claim 7, *Verard* discloses wherein the imaging device is used during surgery (Column 2, Lines 44-64). Examiner contends this intra-operative image would "verify" a position of the medical instrument.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,892,090 to *Verard et al.* "*Verard*" in view of U.S. Publication No.

2005/0065434 to *Bavaro et al. "Bavaro"* or U.S. Patent No. 7,366,562 to *Dukesherer et al. "Dukesherer"* as applied to claim 1 above, and further in view U.S. Patent No. 6,198,963 to *Haim et al. "Haim"*.

As for Claim 6, *Verard and Bavaro/Dukesherer* disclose a device for determining the position of an instrument in a vascular system comprising more than one electromagnetic tracking sensor attached to a medical instrument (e.g. catheter) as described above. Furthermore, *Verard* discloses using the "statistical methods" to determine if the surgical instrument has potentially punctured the vessel by determining if the reported position is too far from the centerline or the trajectory of the path traveled is greater than a certain angle (worst case 90 degrees) with respect to the vessel. Examiner notes that *Verard and Bavaro* does not expressly disclose outputting a warning on the display.

Haim teaches from within a similar field of endeavor with respect to locating a medical device within the body using a sensor affixed to the distal end (Column 9, Lines 18-30 and 53-60). *Haim* further teaches acquiring a vector relating to the location of the sensor and processing the vector to check for errors such as "*values beyond a predetermined acceptable range*" (Column 9, Line 61-Column 10, Line 10). If the measurement was not successful (e.g. beyond the predetermined range) a warning signal is visually or audibly conveyed to the user (Column 9, Lines 45-51; Column 10, Lines 11-21).

Therefore, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the device for determining the

position of an instrument within the body as described by *Verard and Bavaro/Dukesherer* to visually warn the user on a display if the measured/corrected spatial location exceeds a predefined threshold as described by *Haim* in order to prevent the interventional device from breaching vessel walls and disrupting vital organs.

Response to Arguments

9. Applicant's arguments with respect to claims 1-10 have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection. However, Examiner will address any issues which may pertain to the current rejection. For example, Applicant has argued that "*Dukesherer and Haim are introduced for allegedly showing elements of the dependent claims and as such, do nothing to cure the deficiencies in Verard*". Examiner respectfully disagrees, especially when limitations addressed by *Dukesherer* (e.g. taking into account a distance between the first and second localizers) are now incorporated into Claim 1. As described in the rejection above, both *Dukesherer* and *Bavaro* teach wherein it is considered a well-known expedient in the art to utilize fixed or known distances between localizers to compensate for error. Adding this information to the correcting means as described by *Verard* appears to provide a display of an "optimized" quality dimension, in that the localizers are accurately represented in a display.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER COOK whose telephone number is (571)270-7373. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. C./
Examiner, Art Unit 3737

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737